

PHS 352.380-4

48 CFR Ch. 3 (10-1-96 Edition)

OFFERORS SHALL FURNISH THE FOLLOWING INFORMATION, AS APPLICABLE, FOR CONTAINERS

Appli- cable item No.	Type and size of container	Quan- tity	Free loan period	Demurrage charges per day per cyl- inder
Replacement value for each container		Identification and location of offeror's car- rier for return of empty container		

(c) When the offeror indicates that containers have a replacement value of less than \$10, the Government shall have the option to purchase containers and add the cost to the offered price. When purchase option is exercised, offers shall be evaluated accordingly. In this event, the container shall become the property of the Government.

(End of clause)

Subpart PHS 352.3—Provision and Clause Matrices

PHS 352.380-4 Contract clauses for contracts awarded under the Indian Self-Determination Act.

(a) PHS Acquisition Regulations (PHSAR) Clauses for Cost-Reimbursement Contracts Awarded under the Indian Self-Determination Act.

Number, PHSAR Clause No., and Title and Date of Clause

1. 352.280-4(a)(1) Definitions. (June 1977)
2. 352.280-4(a)(2) Disputes. (June 1977)
3. 352.280-4(a)(3) Limitation of Cost. (June 1977)
4. 352.280-4(a)(4) Allowable Cost. (June 1977)
5. 352.280-4(a)(5) Negotiated Overhead Rates. (June 1977)
6. 352.280-4(a)(6) Payment (June 1977)
7. 352.280-4(a)(7) Advance Payment. (June 1977)
8. 352.280-4(a)(8) Examination of Records. (June 1977)
9. 352.280-4(a)(9) Inspection and Reports. (June 1977)
10. 352.280-4(a)(10) Subcontracting. (June 1977)
11. 352.280-4(a)(11) Accounts, Audit, and Records. (June 1977)
12. 352.280-4(a)(12) Government Property. (June 1977)
13. 352.280-4(a)(13) Changes. (June 1977)
14. 352.280-4(a)(14) Notice to the Government of Delays. (June 1977)
15. 352.280-4(a)(15) Retrocession. (June 1977)

16. 352.280-4(a)(16) Reassumption of Programs. (June 1977)
17. 352.280-4(a)(17) Key Personnel. (June 1977)
18. 352.280-4(a)(18) Litigation and Claims. (June 1977)
19. 352.280-4(a)(19) Indemnity and Insurance. (June 1977)
20. 352.280-4(a)(20) Overtime. (June 1977)
21. 352.280-4(a)(21) Foreign Travel. (June 1977)
22. 352.280-4(a)(22) Questionnaires and Surveys. (June 1977)
23. 352.280-4(a)(23) Printing. (June 1977)
24. 352.280-4(a)(24) Services of Consultants. (June 1977)
25. 352.280-4(a)(25) Assignment of Claims. (June 1977)
26. 352.280-4(a)(26) Contract Work Hours and Safety Standards Act-Overtime Compensation. (June 1977)
27. 352.280-4(a)(27) Walsh-Healey Public Contracts Act. (June 1977)
28. 352.280-4(a)(28) Equal Opportunity. (June 1977)
29. 352.280-4(a)(29) Indian Preference in Training and Employment. (June 1977)
30. 352.280-4(a)(30) Certificate of Nonsegregated Facilities. (June 1977)
31. 352.280-4(a)(31) Convict Labor. (June 1977)
32. 352.280-4(a)(32) Officials not to Benefit. (June 1977)
33. 352.280-4(a)(33) Buy American Act Supply and Service contracts. (June 1977)
34. 352.280-4(a)(34) Anti-Kickback Act. (June 1977)
35. 352.280-4(a)(35) Use of Indian Business Concerns. (June 1977)
36. 352.280-4(a)(36) Payment of Interest on Contractors' Claims. (June 1977)
37. 352.280-4(a)(37) Fair and Equal Treatment of Indian People. (June 1977)
38. 352.280-4(a)(38) Price Reduction for Defective Cost or Pricing Data. (June 1977)
39. 352.280-4(a)(39) Subcontractor Cost and Pricing Data. (June 1977)
40. 352.280-4(a)(40) Penalties. (June 1977)
41. 352.280-4(a)(41) Effect on Existing Rights. (June 1977)
42. 352.280-4(a)(42) General Services Administration Supply Sources. (June 1977)

(b) PHSAR Clauses for Fixed-Price Contracts Awarded under the Indian Self-Determination Act.

Number, PHSAR Clause No. and Title and Date of Clause

1. 352.280-4(b)(1) Definitions. (June 1977)
2. 352.280-4(b)(2) Disputes. (June 1977)
3. 352.280-4(b)(3) Contract Work Hours and Safety Standards Act-Overtime Compensation. (June 1977)
4. 352.280-4(b)(4) Walsh-Healey Public Contracts Act. (June 1977)
5. 352.280-4(b)(5) Convict Labor. (June 1977)

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6. 352.280–4(b)(6) Notice to the Government of Delays. (June 1977)
7. 352.280–4(b)(7) Assignment of Claims. (June 1977)
8. 352.280–4(b)(8) Officials not to Benefit. (June 1977)
9. 352.280–4(b)(9) Anti-Kickback Act. (June 1977)
10. 352.280–4(b)(10) Penalties. (June 1977)
11. 352.280–4(b)(11) Buy American Act. (June 1977)
12. 352.280–4(b)(12) Equal Opportunity. (June 1977)
13. 352.280–4(b)(13) Certificate of Nonsegregated Facilities. (June 1977)
14. 352.280–4(b)(14) Subcontracting. (June 1977)
15. 352.280–4(b)(15) Competition in Subcontracting. (June 1977)
16. 352.280–4(b)(16) Use of Indian Business Concerns. (June 1977)
17. 352.280–4(b)(17) Indian Preference in Training and Employment. (June 1977)
18. 352.280–4(b)(18) Inspection. (June 1977)
19. 352.280–4(b)(19) Changes. (June 1977)
20. 352.280–4(b)(20) Retrocession. (June 1977)
21. 352.280–4(b)(21) Assumption and Reassumption of Contract Programs. (June 1977)
22. 352.280–4(b)(22) Payment of Interest on Contractor's Claims. (June 1977)
23. 352.280–4(b)(23) Government-Furnished Property. (June 1977)
24. 352.280–4(b)(24) Examination of Records by the Comptroller General. (June 1977)
25. 352.280–4(b)(25) Indemnity and Insurance. (June 1977)
26. 352.280–4(b)(26) Fair and Equal Treatment of Indian People. (June 1977)
27. 352.280–4(b)(27) Reports to the Indian People and Annual Reports. (June 1977)
28. 352.280–4(b)(28) Questionnaires and Surveys. (June 1977)
29. 352.280–4(b)(29) Printing. (June 1977)
30. 352.280–4(b)(30) Price Reduction for Defective Cost or Pricing. (June 1977)
31. 352.280–4(b)(31) Subcontractor Cost and Pricing Data. (June 1977)
32. 352.280–4(b)(32) Advance Payment. (June 1977)
33. 352.280–4(b)(33) Effect on Existing Rights. (June 1977)
34. 352.280–4(b)(34) Federal, State, and Local Taxes. (June 1977)

SUBCHAPTER T—PHS SUPPLEMENTATIONS

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 PHS 380.502-4 Buy Indian contract.
 PHS 380.502-5 Buy Indian restricted advertising.
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AUTHORITY: 5 U.S.C. 301; 40 U.S.C. 486(c).

SOURCE: 49 FR 36263, Sept. 14, 1984, unless otherwise noted.

Subpart PHS 380.1—Acquisitions Involving Human Subjects

SOURCE: 51 FR 20491, June 5 1986, unless otherwise noted.

PHS 380.101 Applicability.

This subpart applies to all research and development contracts involving human subjects except those that are exempt by Secretarial waiver under 45 CFR 46.101(e) or exempt under 45 CFR 46.101(b).

PHS 380.102 Policy.

(a) Safeguarding the rights and welfare of human subjects in activities under Public Health Service (PHS) research and development contracts is the responsibility of each institution that receives or is accountable to PHS for funds awarded for the conduct of that activity. To assure that this institutional responsibility is met, PHS shall not permit a nonexempt research activity involving human subjects to be undertaken unless the institution has an assurance on file with the Office for Protection from Research Risks (OPRR), NIH/PHS, and has filed a certification that an institutional review board (IRB) has reviewed and approved the activity in accordance with 45 CFR Part 46.

(b) Contracts involving human subjects will not be awarded to an individual unless he/she is affiliated with or sponsored by an institution which can and will assume responsibility for safeguarding the human subjects involved.

PHS 380.103 Assurances.

In accordance with 45 CFR 46.103, OPRR is responsible for negotiation of assurances covering all PHS-supported research activities involving human subjects. Consultation with OPRR (telephone: 301-496-7041) is recommended on issues regarding assurances, certification of IRB review and approval, and interpretation of the regulations for the protection of human subjects in 45 CFR Part 46.

PHS 380.104 Notice to offerors.

Solicitations shall contain the notice to offerors set forth in PHS 352-280-1(a) whenever contract performance is expected to involve human subjects.

PHS 380.105 Contract clause.

The clause set forth in PHS 352.280-1(b) shall be inserted in all contracts involving human subjects.

Subpart PHS 380.2—Acquisitions Involving the Use of Laboratory Animals

SOURCE: 51 FR 20492, June 5 1986, unless otherwise noted.

PHS 380.201 Scope of subpart.

This subpart describes Public Health Service (PHS) contracts for projects or activities involving animals, and the responsibilities of the PHS agencies and subordinate elements for implementing policies and procedures described herein.

PHS 380.202 Definitions.

(a) *Animal*. Any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes.

(b) *Animal facility*. Any building, room, area, enclosure, or vehicle, including satellite facility, used for animal confinement, transport, maintenance, breeding or experiments of sur-

gical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

(c) *Animal Welfare Act*. Pub. L. 89-544, 1966, as amended (Pub. L. 91-579 and Pub. L. 94-279) 7 U.S.C. 2131 et seq. Implementing regulations are published in the Code of Federal Regulations (CFR), Title 9, Subchapter A, Parts 1, 2, 3, and 4, and are administered by the U.S. Department of Agriculture.

(d) *Animal Welfare Assurance or Assurance*. The documentation from an awardee or a prospective awardee institution assuring institutional compliance with this policy.

(e) *Guide. Guide for the Care and Use of Laboratory Animals*, NIH Pub. No. 85-23, 1985 edition or succeeding revised editions.

(f) *Institution*. Any public or private organization, business, or agency (including components of Federal, State and local governments).

(g) *Institutional official*. An individual who has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirement of this subpart will be met.

(h) *Public Health Service*. The Public Health Service includes the Office of the Assistant Secretary for Health; the Alcohol, Drug Abuse, and Mental Health Administration; the Centers for Disease Control; the Food and Drug Administration; the Health Resources and Services Administration; and the National Institutes of Health.

(i) *Quorum*. A majority of the members of the Institutional Animal Care and Use Committee.

PHS 380.203 Policy.

It is the policy of PHS to require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training and biological testing (hereinafter referred to as activities) supported by PHS. PHS endorses the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training" developed by the Interagency Research Animal Committee (IRAC). This policy is

intended to implement and supplement those Principles.

PHS 380.204 Applicability.

(a) This policy is applicable to all PHS-supported activities involving animals, whether the activities are performed at an awardee institution, or any other institution, in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States. Institutions in foreign countries receiving PHS support for activities involving animals shall comply with this policy, or provide evidence to PHS that acceptable standards for the humane care and use of the animals in PHS-supported activities will be met.

(b) No PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with this policy for PHS-supported activities, or unless the individual makes other arrangements with PHS.

(c) This policy does not supercede or preempt applicable State or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act, and other Federal statutes and regulations relating to animals.

PHS 380.205 Contractor implementation.

(a) *Animal Welfare Assurance.* No activity involving animals will be supported by PHS until the institution conducting the activity has provided a written Assurance acceptable to PHS, setting forth compliance with the policy in this subpart for PHS-supported activities. Assurances shall be submitted to OPRR, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 4B09, Bethesda, Maryland 20892. The Assurance shall be typed on the institution's letterhead and signed by an institutional official. OPRR will provide the applicant institution with necessary instructions and an example of an acceptable Assurance. All Assurances submitted to PHS in accordance

with the policy will be evaluated by OPRR to determine the adequacy of the institution's proposed program for the care and use of animals in PHS-supported activities. On the basis of this evaluation, OPRR may approve or disapprove the Assurance, or negotiate an acceptable Assurance with the institution. Approval of an Assurance will be for a specified period of time (no longer than five years) after which time the institution must submit a new Assurance to OPRR. OPRR may limit the period during which any particular approved Assurance shall remain effective or otherwise condition, restrict, or withdraw approval. Without an applicable PHS approved Assurance, no PHS-supported activity involving animals at the institution will be permitted to continue.

(1) *Institutional program for animal care and use.* The Assurance shall fully describe the institution's program for the care and use of animals in PHS-supported activities. PHS requires institutions to use the *Guide for the Care and Use of Laboratory Animals (Guide)* as a basis for developing and implementing an institutional program for activities involving animals. The program description must include the following:

(i) A list of every branch and major component of the institution, as well as a list of every branch and major component of any institution which is to be included under the Assurance;

(ii) The lines of authority and responsibility for administering the program and ensuring compliance with this policy;

(iii) The qualifications, authority and responsibility of the veterinarian(s) who will participate in the program;

(iv) The membership list of the Institutional Animal Care and Use Committee(s) (IACUC)¹ established in accordance with the requirements set forth in this subpart;

¹The name Institutional Animal Care and Use Committee (IACUC) as used in this policy is intended as a generic term for a committee whose function is to ensure that the